



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16, 225, 500, 507, and 579

[Docket No. FDA-2011-N-0922]

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals; Public Meeting on Proposed Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meeting.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing three public meetings to discuss the proposed rule to establish requirements for current good manufacturing practice and hazard analysis and risk-based preventive controls for animal food. This proposed rule is one of several proposed rules that will establish the foundation of, and central framework for, the modern food safety system envisioned by Congress in the FDA Food Safety Modernization Act (FSMA). The purpose of the public meetings is to inform the public of the provisions of the proposed rule and the rulemaking process (including how to submit comments, data, and other information to the rulemaking docket) as well as solicit oral stakeholder and public comments on the proposed rule and to respond to questions about the proposed rule.

DATES: See section II, “How to Participate in the Public Meetings,” in the

SUPPLEMENTARY INFORMATION section.

ADDRESSES: See section II, “How to Participate in the Public Meetings,” in the

SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT: For general questions about the meeting, for assistance to register for the meeting, to request an opportunity to make an oral presentation, or to request special accommodations due to a disability, contact: Aleta Sindelar, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., rm. 133, Rockville, MD 20855, 240-276-9230, FAX: 240-276-9241, email: aleta.sindelar@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FSMA (Public Law 111-353) was signed into law by President Obama on January 4, 2011, to better protect public health by helping to ensure the safety and security of the food supply. FSMA amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish the foundation of a modernized, prevention-based food safety system. Among other things, FSMA requires FDA to issue regulations requiring preventive controls for human food and animal food, set standards for produce safety, and require importers to have a program to verify that the food products they bring into the United States are produced in a manner consistent with applicable FDA food safety requirements.

FSMA was the first major legislative reform of FDA's food safety authorities in more than 70 years, even though FDA has increased the focus of its food safety efforts on prevention over the past several years. The proposed rule for preventive controls for food for animals can be found elsewhere in this issue of the Federal Register, and it establishes a docket so that the public can review the proposed rule and submit comments to FDA. This proposed rulemaking is one of several key proposals in furtherance of FSMA's food safety mandate.

The proposed rule would establish regulations regarding the manufacturing, processing, packing, or holding of animal food in two ways. First, it would create new current good

manufacturing practice (CGMP) regulations that specifically address the manufacturing, processing, packing, and holding of animal food. Second, it would include new preventive control provisions intended to implement section 103 of FSMA for animal food. In general, with some exceptions the new preventive control provisions would apply to animal food facilities that are required to register with FDA under the FD&C Act. These preventive controls would include requirements for covered facilities to maintain a food safety plan, perform a hazard analysis, and institute preventive controls for the mitigation of those hazards. Facilities would also be required to monitor their controls, verify that they were effective, take appropriate corrective actions, and maintain records documenting these actions.

For information on the proposed rule for preventive controls for food for animals and related fact sheets, see FDA's FSMA Web page located at www.fda.gov/FSMA.

II. How to Participate in the Public Meetings

FDA is holding the public meetings on the proposed rule for preventive controls for food for animals to inform the public about the proposed rule and the rulemaking process, including how to submit comments, data, and other information to the rulemaking docket; to respond to questions about the proposed rule; and to provide an opportunity for interested persons to make oral presentations. Due to limited space and time, FDA encourages all persons who wish to attend the meetings to register in advance. There is no fee to register for the public meetings, and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited. Onsite registration will be accepted, as space permits, after all preregistered attendees are seated.

Those requesting an opportunity to make an oral presentation during the time allotted for public comment at the meeting are asked to submit a request and to provide the specific topic or

issue to be addressed. Due to the anticipated high level of interest in presenting public comment and limited time available, FDA is allocating 3 minutes to each speaker to make an oral presentation. Speakers will be limited to making oral remarks; there will not be an opportunity to display materials such as slide shows, videos, or other media during the meeting. If time permits, individuals or organizations that did not register in advance may be granted the opportunity to make an oral presentation. FDA would like to maximize the number of individuals who make a presentation at the meeting and will do our best to accommodate all persons who wish to make a presentation or express their opinions at the meeting.

FDA encourages persons and groups who have similar interests to consolidate their information for presentation by a single representative. After reviewing the presentation requests, FDA will notify each participant before the meeting of the approximate time their presentation is scheduled to begin, and remind them of the presentation format (i.e., 3-minute oral presentation without visual media).

While oral presentations from specific individuals and organizations will be necessarily limited due to time constraints during the public meeting, stakeholders may submit electronic or written comments discussing any issues of concern to the administration record (the docket) for the rulemaking. All relevant data and documentation should be submitted with the comments to Docket No. FDA-2011-N-0922. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number FDA-2011-N-0922. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Table 1 of this document provides information on participation in the public meetings:

Table 1.--Information on Participation in the Meetings and on Submitting Comments to the Rulemaking Dockets

	Date	Electronic Address	Address	Other Information
College Park, MD, Public meeting	November 21, 2013, from 8:30 a.m. to 2:30 p.m.	This meeting will be available for public viewing via Adobe Connect at https://collaboration.fda.gov/r4g7zwj0vea/ at the time of the meeting.	Wiley Auditorium, Harvey W. Wiley Federal Bldg., 5100 Paint Branch Pkwy., College Park, MD 20740	Onsite registration from 8 a.m. to 8:30 a.m.
College Park, MD, Advance registration	By November 19, 2013	Individuals who wish to participate in person are asked to preregister at http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm	We encourage you to use electronic registration if possible. ¹	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.
College Park, MD, Request to make an oral presentation	By November 14, 2013	http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm ²		Requests made on the day of the meeting to make an oral presentation will be granted as time permits. Information on requests to make an oral presentation may be posted without change to http://www.regulations.gov , including any personal information provided.
College Park, MD, Request special accommodations due to a disability	By November 14, 2013	Aleta Sindelar, email: aleta.sindelar@fda.hhs.gov	See FOR FURTHER INFORMATION CONTACT	
College Park, MD, Submit electronic or written comments	By [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]	Docket No. FDA 2011-N-0922		
Chicago, IL, Public meeting	November 25, 2013, from 8:30 a.m. to 2:30 p.m.		Ralph Metcalfe Federal Building, 77 West Jackson Blvd., Chicago, IL 60604	Onsite registration from 8 a.m. to 8:30 a.m.

Table 1.--Information on Participation in the Meetings and on Submitting Comments to the Rulemaking Dockets

	Date	Electronic Address	Address	Other Information
Chicago, IL, Advance registration	By November 21, 2013	Individuals who wish to participate in person are asked to preregister at http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm	We encourage you to use electronic registration if possible. ¹	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.
Chicago, IL, Request to make an oral presentation	By November 18, 2013	http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm ²		Requests made on the day of the meeting to make an oral presentation will be granted as time permits. Information on requests to make an oral presentation may be posted without change to http://www.regulations.gov , including any personal information provided.
Chicago, IL, Request special accommodations due to a disability	By November 18, 2013	Aleta Sindelar, email: aleta.sindelar@fda.hhs.gov	See FOR FURTHER INFORMATION CONTACT	
Chicago, IL, Submit electronic or written comments	By [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]	Docket No. FDA 2011-N-0922		
Sacramento, CA, Public meeting	December 6, 2013, from 8:30 a.m. to 2:30 p.m.	This meeting will be available for public viewing via Adobe Connect https://collaboration.fda.gov/dec_6_fda_fsma_public_meeting/	Stanford Room, 650 Capitol Mall, Sacramento, CA 95814	Onsite registration from 8 a.m. to 8:30 a.m.
Sacramento, CA, Advance registration	By December 4, 2013	Individuals who wish to participate in person are asked to preregister at http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm	We encourage you to use electronic registration if possible. ¹	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.

Table 1.--Information on Participation in the Meetings and on Submitting Comments to the Rulemaking Dockets

	Date	Electronic Address	Address	Other Information
Sacramento, CA, Request to make an oral presentation	By November 29, 2013	http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm ²		Requests made on the day of the meeting to make an oral presentation will be granted as time permits. Information on requests to make an oral presentation may be posted without change to http://www.regulations.gov , including any personal information provided.
Sacramento, CA, Request special accommodations due to a disability	By November 29, 2013	Aleta Sindelar, email: aleta.sindelar@fda.hhs.gov	See FOR FURTHER INFORMATION CONTACT	
Sacramento, CA, Submit electronic or written comments	By [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]	Docket No. FDA 2011-N-0922		

¹ You may also register via email, mail, or FAX. Please include your name, title, firm name, address, and phone and FAX numbers in your registration information and send to: Aleta Sindelar, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., rm. 133, Rockville, MD 20855, 240-276-9230, FAX: 240-276-9241, email: aleta.sindelar@fda.hhs.gov. Onsite registration will also be available.

² You may also request to make an oral presentation at the public meeting via email. Please include your name, title, firm name, address, and phone and FAX numbers as well as the full text, comprehensive outline, or summary of your oral presentation and send to: Aleta Sindelar, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., rm. 133, Rockville, MD 20855, 240-276-9230, FAX: 240-276-9241, email: aleta.sindelar@fda.hhs.gov.

III. Comments, Transcripts, and Recorded Video

Information and data submitted voluntarily to FDA during the public meeting will become part of the administrative record for the rulemaking and will be accessible to the public at <http://www.regulations.gov>. The transcript of the proceedings from the public meeting will become part of the administrative record for the rulemaking. Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>, Docket No. FDA-2011-N-0922, and at FDA's FSMA Web site at:

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>. It may also be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Additionally, FDA will be recording the meeting via adobe connect on November 21, 2013. Once the recording has been made 508 compliant, it will be accessible at FDA's FSMA Web site at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>.

Dated: October 22, 2013.

Leslie Kux,
Assistant Commissioner for Policy.